K102903

510(k) SUMMARY

Pioneer Cannulated Screw System

Sponsor: Manufacturer: Pioneer Surgical Technology
375 River Park Circle
Marquette, MI 49855

Official Contact: Emily M. Downs
Phone: (906) 225-5602
Fax: (906) 226-4459

OCT 2 0 2010

Date prepared: October 20, 2010

Device Name: Pioneer Cannulated Screw System

Classification Name: The classification of the Pioneer Cannulated Screw System is Class II, as per the Code of Federal Regulations, Title 21:
21 CFR 888.3040: Smooth or threaded metallic bone fixation fastener.
21CFR 888.3030: Single/multiple component metallic bone fixation appliances and accessories

Product Code: *Product Code: HWC: Screw, Fixation, and HTN: washer, bolt nut*
The Panel code is 87.

Predicate Device: K003496 – Pioneer Cannulated Screw System (SE 02/08/2001)
K021932 – Synthes 6.5mm Cannulated Screw (SE 9/6/2002)
K962011 – Synthes 7.0/7.3mm Cannulated Screw (SE 8/5/1996)

Description: The Cannulated Screw System by Pioneer consists of cannulated screws of varying diameters, thread configurations, and lengths to accommodate variations in surgical technique, severity level of fracture, and differing patient anatomy. The screws are available in self-tapping or self-drilling, in partially and fully threaded configurations, in diameters ranging from 3.5mm – 7.5mm and lengths ranging from 8-200mm. The system also includes correspondingly sized washers, the use of which is optional. The purpose of this submission is to extend the available screw lengths to 200mm.

The screws and washers are manufactured from Biodur 108 (ASTM F2229)

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Intended Use: The Cannulated Screw System by Pioneer will be indicated for use in long and small bone fracture fixation, which may include the following:

1. Fractures of the tarsals and metatarsals;
2. Metatarsal and phalangeal osteotomies;
3. Fractures of the carpals and metacarpals;
4. Carpal and metacarpal arthrodesis;
5. Small fragments of the hand and wrist;
6. Ligament fixation;
7. Sacroiliac joint disruptions;
8. Fractures of the distal femur and proximal tibia;
9. Intracapsular fractures of the hip;
10. Ankle arthrodesis;
11. Pelvis and acetabulum fractures; and
12. Areas where accurate screw placement is vital.

This system is not indicated for use in the spine. The Cannulated Screw System by Pioneer may be offered both sterile and non-sterile and is a single use device.

Material: The Pioneer Cannulated Screw System is composed of the identical material to the predicate Pioneer Cannulated Screw System, Biodur 108 (ASTM F2229).

Comparison to Predicate Devices: The subject device has indication for use, material (Biodur 108), screw diameter (7.0/7.5mm), and mechanism of action identical to the Pioneer Cannulated Screw System (K003496). The subject device has the same maximum length (200mm) as the Synthes Cannulated Screw (K021932).

Non-Clinical Performance Data: Engineering calculations were also provided to demonstrate that under a worst-case bending situation, additional length of screw will not raise new issues of safety or effectiveness.

Performance and SE Determination: Based on the supporting documentation within this premarket notification, the subject device demonstrates substantial equivalence to the listed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

APR 15 2011

Pioneer Surgical Technology, Inc.
% Emily M. Downs
Regulatory Affairs Project Manager
375 River Park Circle
Marquette, Michigan 49855

Re: K102903
Trade/Device Name: Pioneer Cannulated Screw System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC, OUR
Dated: September 29, 2010
Received: September 30, 2010

Dear Ms. Downs:

This letter corrects our substantially equivalent letter of October 20, 2010.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K10 2903

Device Name: Cannulated Screw System

Indications:

The Cannulated Screw System by Pioneer will be indicated for use in long and small bone fracture fixation, which may include the following:

1. Fractures of the tarsals and metatarsals;
2. Metatarsal and phalangeal osteotomies;
3. Fractures of the carpals and metacarpals;
4. Carpal and metacarpal arthrodesis;
5. Small fragments of the hand and wrist;
6. Ligament fixation, if appropriate;
7. Sacroiliac joint disruptions;
8. Fractures of the distal femur and proximal tibia;
9. Intracapsular fractures of the hip;
10. Ankle arthrodesis; and
11. Pelvis and acetabulum fractures; and
12. Areas where accurate screw placement is vital.

This system is not indicated for use in the spine. The Cannulated Screw System by Pioneer will be offered both sterile and non-sterile and is a single use device.

Prescription Use __V__ OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for M. Melkerson

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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